

App. No. 10/626,502
Office Action Dated April 21, 2006

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REMARKS

Favorable reconsideration of this application is respectfully requested in view of the above amendments and the following remarks. Claims 1 and 11 have been amended editorially. No new matter has been added. Claims 1, 8-12, 14, and 16 are pending.

Specification

The specification is objected to for informalities. Applicants respectfully submit that the represented values have been properly converted to be consistent with the revised concentration designations. In particular, the values for mg/dL have been converted to ng/mL using the conversion $1 \text{ mg/dL} = 0.01 \text{ mg/mL} = 10 \text{ ng/mL}$ since $1.0 \text{ dL} = 0.1 \text{ L} = 100 \text{ mL}$. As such, "CRP concentrations (mg/mL)" has been amended to "CRP concentrations (ng/mL)" on page 27, lines 5 and 13, and the values in Tables 1, 2 and 4 have been properly converted to be consistent with the revised concentration designation ng/mL. Applicants respectfully submit that no new matter has been added.

Withdrawal of the objection is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 1 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (U.S. Patent No. 6,248,597) in combination with Shigenobu et al. (WO 02/018953). Applicants respectfully traverse this rejection.

The rejection relies on Shigenobu for a copolymer of a monomer of the general formula [2] and an aralkyl methacrylate. The rejection's reliance on Shigenobu is misplaced. Shigenobu teaches a monomer having a vinyl group that is polymerizable with a monomer having a phosphorylcholine (PC) group. While the reference is not limited to the preferences, nonetheless, Shigenobu discloses methyl (meth)acrylate, ethyl (meth)acrylate, n-butyl (meth)acrylate, isobutyl (meth)acrylate, pentyl (meth)acrylate, hexyl (meth)acrylate, heptyl (meth)acrylate, octyl (meth)acrylate, tridecyl (meth)acrylate, and 2-hydroxyethyl (meth)acrylate as examples of monomers having a vinyl group, and that n-butyl methacrylate (hereinafter "BMA") is particularly preferable. These monomers disclosed by Shigenobu are clearly different from the methacrylate having the aralkyl group as required by claims 1 and 11.

Moreover, as demonstrated in the present specification, the properties of a product obtained by polymerizing methacrylate lacking the aralkyl group with the monomer of the general formula [2], as disclosed by Shigenobu, are unexpectedly different from the properties of

App. No. 10/626,502
Office Action Dated April 21, 2006

a product obtained by polymerizing an aralkyl methacrylate and the monomer of the general formula [2], as required by claims 1 and 11. More particularly, the absorbance values in the immunoassays of PSA, CRP and RF were compared between the copolymer of BMA and MPC (polymer 1) and the homopolymer of MPC (polymer 6), which are polymers used in the Examples of Shigenobu, and the copolymer of benzyl methacrylate and MPC (polymer 5). As shown in Table 1, polymer 5 showed a superior agglutination accelerating action as compared to polymers 1 and 6 for the immunoassay of PSA (see page 21, lines 8-9). On the other hand, as shown in Tables 5, polymer 1 showed better results as compared to polymer 5 for the immunoassay of CRP (see page 29), and as shown in Table 7, polymer 5 did not perform as well as the other polymers for the immunoassay of RF (see page 35). The present findings indicate that the use of the copolymer of MPC and aralkyl methacrylate provides superior measurement sensitivity for the immunoassay of PSA, but not for CRP and RF. These unexpected results are suggested neither by Eda nor by Shigenobu. In fact, the two Examples in Eda for the immunoassays of PSA and CRP only involve the use of polystyrene, and the four Reference Examples in Shigenobu only involve the use of one type of copolymer, namely BMA and MPC. Neither reference suggests any reason to expect that better results would be achieved with other copolymers.

In view of the above, Applicants respectfully submit that claims 1 and 11 and the dependent claims therefrom are patentable over Eda and Shigenobu, taken together or separately.

Favorable consideration and withdrawal of the rejection are respectfully requested.

Claims 8, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eda and Shigenobu, in further view of Craig et al. (US 4,401,765). Applicants respectfully traverse this rejection.

Eda and Shigenobu have been distinguished above. Craig does not remedy the deficiencies of Eda and Shigenobu.

More particularly, Craig is directed to a particle reagent consisting of a core polymer having a high refractive index. The reference discloses that materials for the core polymers are restricted to those with high refractive indices so that the core polymer will produce acceptable signal changes (col. 4, lines 61-65). The signal changes result from the changes in the particle size during the agglutination reaction (col. 4, lines 57-8). As such, these core polymers correspond at best, to the carrier or latex for immobilizing an antibody in the agglutination assay

App. No. 10/626,502
Office Action Dated April 21, 2006

of the present invention, not the agglutination accelerator. The rejection assumes that higher sensitivity can be achieved by optimizing the refractive index of the agglutination accelerator. On the contrary, the agglutination accelerator itself does not require any light scattering response to obtain superior results in the present invention.

Moreover, the reference provides no motivation to use the core polymer as an agglutination accelerator, or to use a copolymer having benzyl methacrylate and the monomer of the general formula [2] as an agglutination accelerator to obtain the advantageous effects described above. In addition, the reference discloses a list of 95 polymerized monomers that could be used, including poly(benzyl methacrylate), but notes that not all polymers listed can be utilized since there are additional criteria that need to be applied (col. 6, lines 49-52). As such, it is not even clear whether poly(benzyl methacrylate) is an appropriate substitute, given that benzyl methacrylate is not used in any of the Examples. Further, Craig, as well as Eda and Shigenobu fail to suggest any significant differences in effects using a copolymer with different monomers than those employed. As such, the references actually support the position that the present findings for the copolymers of the monomer of the general formula [2] and aralkyl methacrylate are unexpected.

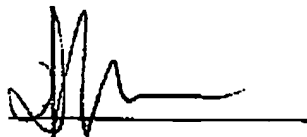
In view of the above, Applicants respectfully submit that claims 8, 14 and 16 are patentable over Eda, Shigenobu and Craig taken separately or together.

Favorable consideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully Submitted,

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